REMARKS

Upon entry of the present amendments, claims 6-11 constitute the pending claims in the present application. Claims 1-5 were previously cancelled. Claims 1-11 stand rejected.

1. Summary of Telephonic Interview and Amendments

Applicants appreciate the time and attention of Examiners Christopher Stone and Patricia Duffy during the productive telephonic interview of January 16, 2009. During the interview, the outstanding rejections of the present claims over 35 U.S.C. §§ 112 and 102 were discussed. Specifically, **agreement was reached** that deletion of "prevention" from claim 6 would overcome the present rejection under 35 U.S.C. § 112, first paragraph. Additionally, **agreement was reached** that a clarifying amendment reflecting that the patient recited in claim 6 is one "having a neurodegenerative disease of the central nervous system" would overcome the present rejection under 35 U.S.C. § 102(b). Finally, the Office indicated that, on overcoming the instant rejection under 35 U.S.C. § 102(b), the scope of the search and examination would be expanded beyond the elected group.

Accordingly, Applicants have amended claim 6 to more particularly define the claimed invention. Specifically, Applicants have deleted "prevention." Applicants have also amended claim 6 for clarity to recite that the patient is one "having a neurodegenerative disease of the central nervous system." No new matter is added by these amendments. Applicants reserve the right to pursue claims to subject matter deleted from the claims as amended herein in one or more applications claiming priority to the instant application.

Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Office will be addressed below in the order they appear in the prior Office Action.

2. Election/Restrictions

The Office has rendered final the restriction of the search and examination of the instant application to (+)-*R*-N-[2-hydroxy-3-(1-piperidinyl)-propoxy]-pyridine-1-oxide-3-carboximidoyl chloride citrate and amyotrophic lateral sclerosis (ALS), contending that (+)-*R*-N-[2-hydroxy-3-

(1-piperidinyl)-propoxy]-pyridine-1-oxide-3-carboximidoyl chloride is known and thus cannot constitute a special technical feature in accordance with PCT Rule 13.1

Applicants respectfully highlight that the present claims as currently amended all share the special technical feature of administering N-[2-hydroxy-3-(1-piperidinyl)-propoxy]-pyridine-1-oxide-3-carboximidoyl chloride to a patient having a neurodegenerative disease of the central nervous system. The reference cited on page 2 of the September 24, 2008 Restriction Requirement, WO 00/50403, does not teach or suggest this technical feature, nor does any other art of record. As such, Applicants request that the search and examination of the pending claims be expanded to encompass the full scope of the corresponding generic claims as per MPEP § 809.02(a) and 37 C.F.R. § 1.141(a).

3. Claim Rejections – 35 U.S.C. § 112, First Paragraph – Claims 6-12

Claims 6-12 are rejected under 35 § U.S.C. 112, first paragraph. The Office acknowledges that the specification enables treatment of ALS but asserts that the specification does not enable the prevention of ALS. While Applicants disagree with the Office's conclusion and note that an evaluation of enablement under the standard established in *In re Wands* (858 F.2d 731, 737 (Fed. Cir. 1988); see also MPEP § 2164.01) has not been performed by the Office, solely to advance prosecution, Applicants have amended claim 6 to no longer recite "preventing." Accordingly, Applicants submit that this rejection has been rendered moot and request reconsideration and withdrawal.

4. Claim Rejections – 35 § U.S.C. 102 – Claims 6-12

Claims 6-12 are rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Biro et al., WO 03/026653 ("Biro"). Applicants respectfully traverse the rejection to the extent that it is maintained over the claims as currently amended.

The Office contends that Biro teaches the administration of *R*-N-[2-hydroxy-3-(1-piperidinyl)-propoxy]-pyridine-1-oxide-3-carboximidoyl chloride or its citric acid salt to a patient. The Office also acknowledges, however, that Biro does not teach or suggest treating ALS. The claims amended herein require administration of N-[2-hydroxy-3-(1-piperidinyl)-

propoxy]-pyridine-1-oxide-3-carboximidoyl chloride to a patient "having a neurodegenerative disease of the central nervous system," such as ALS. Biro does not teach or suggest this feature of the pending claims and instead mentions a method of treatment of diabetic neuropathy (see Biro abstract, which is a peripheral nervous system condition.

Evidence that diabetic neuropathy is a disease of the peripheral and not the central nervous system is provided by the accompanying scientific publications, which have been peer-reviewed by experts in the field and which were published before the filing of the present application. Exhibit A, for example, is a February 12, 2007 publication from the National Institute of Neurological Disorders and Stroke in which the first paragraph explains that diabetic neuropathy is a peripheral nerve disorder caused by diabetes. Moreover, in Exhibit B, the submitted excerpt from Chapter 36 ("Neuropathy") of the 1999 *textbook* "Basic Neurochemistry, Molecular, Cellular, and Medical Aspects," 6th ed., diabetic neuropathy is characterized in the first paragraph as a disorder that is peripheral nervous system-*specific* and not as a disease that affects both the peripheral and central nervous systems (see also page 5 of Exhibit B, "Diabetes mellitus is the most common cause of peripheral neuropathy in the United States"). Additionally, Exhibit C is a 2006 *review* article that also teaches in the first sentence that diabetic neuropathy is a result of peripheral nerve dysfunction. Hence, the weight of Exhibits A, B, and C demonstrates that the skilled artisan would have appreciated that a diabetic neuropathy is a disease of the peripheral nervous system, which falls outside the ambit of claim 1 as amended herein.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference (see MPEP § 2131, quoting *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987)). Biro does not teach or suggest administering a compound to a patient "having a neurodegenerative disease of the central nervous system," as required by the amended claims. Accordingly, this reference cannot sustain the instant anticipation rejection. Applicants request reconsideration and withdrawal of the rejection.

Additionally, the Office alleges that Biro teaches prevention of ALS. While Applicants do not necessarily agree with the Office, as noted above, "prevention" has been deleted from the scope of the claims as amended herein, thus obviating this aspect of the rejection over Biro.

CONCLUSION

In view of the above remarks and amendments, Applicants submit that the pending application is in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at (212) 596-9000.

Applicants believe no fee is due with this response. However, if an additional fee is due, please charge our Deposit Account No. 06-1075, under Order No. 004049-0018-101 from which the undersigned is authorized to draw.

Dated: February 10, 2009

Respectfully submitted,

By _____

Carl A. Morales, Ph.D.
Registration No.: 57,415
ROPES & GRAY LLP
1211 Avenue of the Americas
New York, NY 10036-8704
(212) 596-9000
(212) 596-9090 (FAX)
Attorneys/Agents For Applicants